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| APPLICATION NO.            | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.               | CONFIRMATION NO. |  |
|----------------------------|-------------|----------------------|-----------------------------------|------------------|--|
| 10/086,941                 | 02/26/2002  | Brigitte Chau Phan   | BT12 7506<br>00103502(USP2)USP7X1 |                  |  |
| 7590 06/09/2004            |             |                      | EXAMINER                          |                  |  |
| William P. Christie        |             |                      | LU, FRANK WEI MIN                 |                  |  |
| CHRISTIE PARKER & HALE LLP |             |                      | 1.0010.00                         |                  |  |
| Post Office Box            | x 7068      | ART UNIT             | PAPER NUMBER                      |                  |  |
| Pasadena, CA               | 91109-7068  | 1634                 |                                   |                  |  |

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |   | Applicatio | n No. | Applicant(s) |  |  |  |  |
|---|---|------------|-------|--------------|--|--|--|--|
| Office Action Summary   |   | 10/086,94  |       | PHAN ET AL.  |  |  |  |  |
|   |   | Examiner   |       | Art Unit     |  |  |  |  |
|   |   | Frank W L  |       | 1634         |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |   |            |       |              |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |            |       |              |  |  |  |  |
| Status  |   |            |       |              |  |  |  |  |
| 1)⊠ Respo   | 1) Responsive to communication(s) filed on 18 March 2004.   |            |       |              |  |  |  |  |
| <i>,</i> —  | This action is <b>FINAL</b> . 2b) This action is non-final.   |            |       |              |  |  |  |  |
| •   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. |            |       |              |  |  |  |  |
| Disposition of Claims   |   |            |       |              |  |  |  |  |
| 4) ⊠ Claim(s) 1-115 is/are pending in the application. 4a) Of the above claim(s) 1-28 and 67-108 is/are withdrawn from consideration.  5) □ Claim(s) is/are allowed.  6) □ Claim(s) is/are rejected.  7) □ Claim(s) is/are objected to.  8) ⊠ Claim(s) 29-66 and 109-115 are subject to restriction and/or election requirement.  |   |            |       |              |  |  |  |  |
| Application Pa  | pers  |            |       |              |  |  |  |  |
| ·   | pecification is objected to by the  |            | T     | <b>-</b>     |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  |   |            |       |              |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |   |            |       |              |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |   |            |       |              |  |  |  |  |
| Priority under 35 U.S.C. § 119  |   |            |       |              |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.   |   |            |       |              |  |  |  |  |
| Attachment(s)   |   |            |       |              |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  Paper No(s)/Mail Date  |   |            |       |              |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application (PTO-152)  Paper No(s)/Mail Date   |   |            |       |              |  |  |  |  |

## **DETAILED ACTION**

## Election/Restrictions

- 1. Applicant's election without traverse of Groups II, claims 29-66 and 109-115 in the reply filed on March 18, 2004 is acknowledged.
- 2. After carefully reviewing Group II, claims 29-66 and 109-115, the examiner considers that further restriction is required. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - IIA. Claim 29-50, drawn to an optical bio-disc, classified in class 435, subclass 287.1.
  - IIB. Claim 51-66, drawn to an optical bio-disc, classified in class 435, subclass 287.1.
  - IIC Claims 109-115, drawn to an optical bio-disc, classified in class 435, subclass 287.1.
- 4. The inventions are distinct, each from the other because of the following reasons:

Groups IIA and IIB are distinct and independent inventions in that they are directed to different products which have different modes of operation, different functions, or different effects. As a result, different and distinct searches will have to be performed. For example, the search required for Group IIA such as tracking groove of claim 29 is not required for Group IIB while the search required for Group IIB such as disc drive assembly of claim 51 is not required for Group IIA.

Groups IIA and IIC are distinct and independent inventions in that they are directed to different products which have different modes of operation, different functions, or different effects. As a result, different and distinct searches will have to be performed. For example, the search required for Group IIA such as tracking groove of claim 29 is not required for Group IIC

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while the search required for Group IIC such as a strand of capture DNA in a target zone is disposed between a center and a outer edge of a substrate in claim 109 is not required for Group IIA.

Groups IIB and IIC are distinct and independent inventions in that they are directed to different products which have different modes of operation, different functions, or different effects. As a result, different and distinct searches will have to be performed. For example, the search required for Group IIB such as disc drive assembly of claim 51 is not required for Group IIC while the search required for Group IIC such as a strand of capture DNA in a target zone is disposed between a center and a outer edge of a substrate in claim 109 is not required for Group IIB.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

- 5. Group IIA contains claims directed to the following patentably distinct species of the claimed invention:
- (1) said capture agent is a strand of DNA (claims 30-32)
- (2) said capture agent is an antibody (claim 33)
- (3) said capture agent is an antigen (claim 34)
- (4) said capture agent is biotin (claim 35)
- (5) said capture agent is streptavidin (claim 36)

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are claims are claims 29 and 37-50.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

- 6. Group IIA also contains claims directed to the following patentably distinct species of the claimed invention:
- (6) said anchor agent is a strand of DNA (claim 41)
- (7) said anchor agent is an antibody (claim 42)
- (8) said anchor agent is an antigen (claim 43)

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(9) said anchor agent is biotin (claim 44)

(10) said anchor agent is streptavidin (claim 45)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are claims 29-40 and 46-50.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

- 8. Group IIA also contains claims directed to the following patentably distinct species of the claimed invention:
- (11) said bead is a capture bead (claim 47)

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(12) said bead is a capture bead (claim 48)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims 29-46 and 50.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

- 9. Group IIB contains claims directed to the following patentably distinct species of the claimed invention:
- (13) said capture agent is an oligonucleotide sequence (claims 52 and 53)
- (14) said capture agent is an antibody (claim 54)

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(15) said capture agent is an antigen (claim 55)

- (16) said capture agent is biotin (claim 56)
- (17) said capture agent is streptavidin (claim 57)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are claims 51 and 58-66.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. Group IIB contains claims directed to the following patentably distinct species of the claimed invention:

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- (18) said anchor agent is associated with said capture bead (claim 63)
- (19) said anchor agent is associated with said report bead (claim 64)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are claims 51-62, 65, and 66.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703)872-9306 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu PSA

June 4, 2004

FRANKLU PATENT EXAMINER